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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/713,098	11/14/2000	Constance H. Zlot	DX01051Q	9675

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DNAX RESEARCH, INC.
LEGAL DEPARTMENT
901 CALIFORNIA AVENUE
PALO ALTO, CA 94304

EXAMINER

EWOLDT, GERALD R

ART UNIT PAPER NUMBER

1644

DATE MAILED: 04/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/713,098

Applicant(s)

ZLOT ET AL.

Examiner

G. R. Ewoldt, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2003 and 22 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11,12,15,21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 11,12,15,21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 11, 12, 15, and newly added Claims 21 and 22 are pending.
2. Applicant's amendments and remarks, filed 10/01/03 and 1/22/04, are acknowledged.
3. Applicant argues that Claim 11 is still entitled to the benefit of priority of Provisional Application No. 60/165,438. A review of the application reveals no support for the newly claimed limitations. See section 8, below. Accordingly, the priority date of the instant application is now its own filing date of 11/14/00.
4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).
5. Claims 11, 12, 15, and newly added Claim 22 stand/are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication No. US2002/0064818, for the reasons of record as set forth in the action mailed 6/26/03.

Applicant's arguments, filed 10/01/03, have been fully considered but they are not persuasive. Applicant argues, that "Since US2002/0064818 does not disclose the sequence of residues 1-30 or 286-470 of SEQ ID NO:2 before the priority date of the present application, the reference does not teach each and every element of claim 11 under 35 U.S.C. §102(e)".

The '818 application still teaches a segment of polypeptide with significant identity to residues 286-470 of SEQ ID NO:2 of the instant application (approximately 80 identical amino acids). Accordingly, it remains the Examiner's position that the antibody

of the reference would bind the polypeptide of the instant application, thus, anticipating the antibody and kit of the instant claims.

6. The following are new grounds for rejection necessitated by Applicant's amendment.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 11, 12, 15, and newly added Claims 21 and 22, are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically, the recitation of:

A) A binding compound comprising an antigen binding site from an antibody which specifically binds to residues 1-30 or 286-470 of SEQ ID NO:2 (Claims 11 and 12).

B) The binding compound of Claim 11 wherein the antibody specifically binds to the polypeptide of residues 399-470 of SEQ ID NO:2 (Claim 21).

Applicant's amendment, filed 10/01/03 asserts that no new matter has been introduced into the claims. However, the specification cannot support the new limitations because the specification does not disclose the specific polypeptide fragments of SEQ ID NO:2 (and thus, the claimed antibodies which bind them) of the instant claims. Regarding residues 1-30 of SEQ ID NO:2, the specification discloses only fragments "of at least about" 30 amino acids. Thus, a specific fragment of 30 amino acids is not disclosed. Regarding fragments consisting of residues 286-470 or 399-470 of SEQ ID NO:2, Applicant's arguments seem to be that the fragments (and thus, the antibodies which

bind them) would be obvious. However, obviousness is not the standard in evaluating the introduction of new matter into claims.

9. No claim is allowed.

10. Applicant is advised that should the invention of the previous claims be reintroduced the reintroduction of the previous rejections might be required. However, said reintroduction would be considered a new issue After Final.

11. Applicant's amendment or action (filing of new applications) necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.


13. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Additionally, the Technology Center receptionist can be reached
at (571) 272-1600.

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600


4/5/04
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER